November 2003

VA IRB Bulletin Board

Progress Notes Now Required!!!

As stated previously, VACO has released the new handbook for the protection of research subjects. The new handbook requires that a progress note in CPRS be generated at the time of consent, at the time of subject entry into the protocol, and at the time of termination of participation in the study. We have tried to facilitate generating this progress note by developing a template. The template notes should be created as follows:

- Once the patient has been selected in CPRS, select the "Note" tab.
- Click on the "New Note" button in the bottom left corner of the screen.
- If prompted for a location, select "New Visit" and then "Research & Development" (select the appropriate time of the encounter as well).
- In the progress note title, select "Research – Progress Note" and the appropriate day and time. *If you have progress notes specific to your study, please contact Sola (x52885) regarding requirements of the informed consent, study entry, and termination progress notes.*
- A template page should appear. Select the appropriate event (informed consent, entry into study, or termination from study). Only one event can be entered at a time, but more than one event can appear on the completed progress note.
- Click "OK" until prompted to enter the study title in the white box and then select "OK." If entering information for entry into a study, enter information as prompted in the white boxes as they appear on the screen. When complete, select "OK."
- This will create a progress note. Select the template again to enter template text for another section (ie, to include entry into study at the same time as the consent). All three events can be placed on the same progress note, or they can each be separate progress notes.
- Add any additional text to the progress note that may be useful to your study.
- Sign the progress note.

Please note: the original consent form will be scanned in and attached to your progress note regarding the informed consent session. The original will then be returned to you for inclusion in the study files.

Human Subjects Education

All individuals involved with human subjects research now need to complete the human subjects education requirements annually. If you have not completed the education modules in the past year, these need to be updated by December 15, 2003. Completion certificates and questions should be forwarded to Angie Lacey, at ext.: 51165 or e-mail: angela.lacey@med.va.gov or laceya@ohsu.edu

Research Flag System Updated

The PVAMC has updated the Flag System to meet national standards. This has resulted in a new method to activate research flags, as follows:

Once logged into VISTA, type in "PRF" (for patient record flags) to get to the main menu for activating a flag.

- Type in "**FA**" for "flag activation"
- Type "**SP**" for "select patient"
- **Select** the **patient** as you normally would
- Hit "**return**" until you return to the "record flag assignment " screen.
- Type "**AF**" to assign flag.
- Type in the **Research Flag name**. **Caution:** All flags are now available to each person. Be sure you type in the flag appropriate to your study!!!
- If the appropriate flag pulls up, hit return for "**yes**." If the wrong flag pulls up, type "no" and try again.
- Under "approved by" type "**R&D**" – if given a choice of approving bodies, select RD, Oversight Committee
- In text field, enter the PI's name and pager number, and the title of the study. If appropriate, enter any text that may be useful regarding this patient in this study (ie, state length of participation and start and end-dates, drug assignment if open-label, etc.) **Text must be entered in this field.**
- Type **F1**, then "**E**" to exit text screen.
- Hit "**return**" to assign flag.
- Hit "**return**" to exit flag.

If there are any questions regarding this new system, please contact Sola (x52885), Lisa (x54481) or Shari (x54503).

Always Use Most Current Template

When preparing new study paperwork, always go online to www.visn20.med.va.gov/portlandrd and use all of the most current forms. This is particularly important for the initial review questionnaire (IRQ) and the informed consent form, as both have recently been updated.

VA IRB E-Mail Box

The VA IRB now has an e-mail box. The address is PVAMC-IRB@med.va.gov In order to notify the IRB of an adverse event (prior to submitting the AE report), or in order to send electronic versions of consent forms to the IRB coordinators, please use the address noted here.

New Requirement for Study File Retention

The new VA handbook now requires that study files and related paperwork be maintained by the investigator for six years after the study is terminated. Please retain all paperwork for at least six years, or longer if required by the sponsor. If there are questions regarding this, please do not hesitate to contact the Research Office.